



Transition Memo on the FDA's Center for Food Safety and Applied Nutrition

The FDA's Center for Food Safety and Applied Nutrition (CFSAN) is responsible for ensuring the safety, honest labeling, and healthfulness of the American food supply (except for products containing meat or poultry). The FDA accepts that improved diets could greatly promote health, but it has utterly failed the public in carrying out its mission. One historic cause of FDA's failures is that almost all commissioners (David Kessler was an exception) focused almost exclusively on the seemingly more-exciting drugs and medical devices and largely ignored the public health threats—and opportunities—related to the food supply.

While budget cutbacks are a part of the FDA's and CFSAN's recent failures, the Agency's basic problem is that the Bush administration gave priority to corporate interests instead of the public health. Beyond this great philosophical divide, and resulting from it, we also have seen: politicization of scientific issues, centralization of power in the Office of the Chief Counsel to reduce regulatory actions, failure to provide FDA regional offices with priorities for enforcement actions, focusing on minor concerns about such things as packaging contaminants while ignoring the immediate substantial risks of poor nutrition, obesity, and concomitant diet-related diseases, and others.

On the **food safety** side, CFSAN competes for attention and resources with FDA's drug and medical products safety missions and USDA's responsibility for meat and poultry inspection. As a consequence, food safety has become one of the FDA's highest-profile problems, with recurring wide-scale outbreaks and deaths linked to vegetables, pet food, peanut butter, imported products, and canned foods. Improving public health through safer food will help restore consumer confidence in the FDA, which has fallen to low levels, and simultaneously would play a modest role in reducing health care costs, thereby facilitating the expansion of health care coverage.

Regarding **nutrition**, CFSAN's mission includes promoting a healthier food supply. Achieving that mission could save several hundred thousand lives during the course of the new Administration by reducing the incidence of heart disease, stroke, diabetes, cancer, and other chronic diseases. Achieving that mission also greatly reduce health care costs, thereby facilitating the expansion of health care coverage.

Actions that Could be Undertaken Immediately

FDA-wide

The Obama administration should adopt a policy that **forbids people with conflicts of interest from serving on FDA (and all other government) scientific advisory committees**. Conflicts of interest have been a recurring problem on FDA drug-review committees...so much so, in fact,



that Congress has limited to about 20 percent the number of members who could have conflicts. In keeping with Obama's rejection of lobbyists on transition committees, his donor rolls, and elsewhere, the administration should adopt a government-wide standard of no conflicts.

Food Safety

1. Reconvene the President's Council on Food Safety and provide it with a permanent mission of developing and coordinating a comprehensive food safety agenda. This would establish a body charged with coordinating the 15 agencies currently charged with food safety oversight.
2. Direct OMB to include a section on Food Safety Programs in its Crosscutting Programs chapter of the Analytical Perspectives in future Presidential Budgets. That would raise the profile of food safety as a budget issue, identify total resources directed to food safety efforts across all agencies, and help highlight problems with the fractured food safety structure. It would also perform a coordinating function through OMB by linking together food safety planning at the various agencies.
3. Direct CDC and FDA to immediately engage state and local governments in more effectively tracking and coordinating food safety responses to outbreaks and other food-related emergencies.
4. Reverse FDA policy in pending court cases, and in pronouncements in the *Federal Register*, concerning purported federal preemption of state and local laws that fill gaps in the FDA's regulatory framework or that provide consumers with additional levels of protection beyond that provided in federal law. For example, the FDA misused its authority when it pressured (unsuccessfully) the state of California not to ban the sale of potentially contaminated Gulf Coast oysters and not to alert consumers to the presence in food of cancer-causing acrylamide contamination.

Nutrition

1. Announce that failure by restaurants to disclose the presence of artificial trans fat in their foods would be considered misbranding and a violation of the Food, Drug, and Cosmetic Act;
2. Rescind a policy memo requiring that all warning letters, including those concerning deceptive food labels, be cleared by the Agency's Chief Counsel;
3. Reverse Agency policy in pending court cases, and in pronouncements in the *Federal Register*, concerning purported federal preemption of state and local laws that fill gaps in the FDA's regulatory framework or that provide consumers with additional levels of protection beyond that provided in Federal law;
4. Direct FDA regional offices to conduct systematic reviews of food labels to determine whether they bear false or misleading health-related claims and then issue warning letters to offenders and institute legal actions if manufacturers fail to correct violations. Further,



the Agency's Office of Regulatory Affairs should train inspectors and then direct them to check for misleading claims on food labels while conducting routine inspections. Food labeling violations should be listed on the FDA's web site, as recommended by the GAO.

Priorities for 2009:

CFSAN-wide

1. The FDA's top priority should be to sustain and further **increase CFSAN's budget**. That unit has authority for ensuring the safety and honest labeling of 80 percent of the domestically produced and imported foods. Considering how critically underfunded CFSAN has been and the agency's demonstrated failure to develop effective prevention programs, resulting in numerous high profile outbreaks and recalls in the last two years, the administration needs to sustain efforts that started with the FY 2008 supplemental and FY 2009 CR to meet funding targets set by the FDA Science Board. (A portion of such increases should be applied to improving the nutritional value and honest labeling of the food supply.)
2. The administration should support legislation offered by Sen. Durbin and Rep. DeLauro that would consolidate our fractured food safety system under an **independent Food Safety Administration** that would include both CFSAN and USDA's Food Safety and Inspection Service. At a minimum, the administration should support legislation offered by Rep. DeLauro that would **split FDA into independent agencies overseeing (a) drug/medical devices and (b) foods**, but keep the two agencies within HHS.

Food Safety

1. The administration should support early passage of a law that would:
 - require **food suppliers to have HACCP-style food safety programs and imported foods to be certified as being safe,**
 - **impose modest registration fees that would provide a dedicated stream of funding for the agency, and**
 - **give the FDA the authority to mandate recalls and levy civil penalties.**
2. The administration should quickly finalize the regulation pending for the last four years that would **prevent *Salmonella* contamination of shell eggs**, a significant cause of food-borne illness. The proposal was recently withdrawn from OMB, a technique used to prevent triggering transparency requirements tied to OMB review.
3. The FDA should implement immediate changes to milk and food-code programs by **banning the transport of raw milk** (unless on its way for pasteurization) and including food defense provisions in the food code to protect army PXs. Such emergency steps are too important to wait for action by industry/state review "conferences," which require multi-year reviews and are frequently industry-dominated.
4. The FDA should **require processing of Gulf Coast oysters** to kill *Vibrio vulnificus* as part of the shellfish sanitation codes. State/industry "conferences" have for years failed



to prevent the interstate sale of contaminated oysters, which, like clockwork, cause about 20 gruesome deaths annually.

5. The FDA should act on CSPI's Citizen Petition to issue **on-farm food safety regulations** and traceability requirements to help prevent outbreaks of foodborne illnesses.

Nutrition

1. High sodium levels is the single most harmful aspect of the American diet. According to a 2004 paper by the director of the National Heart, Lung and Blood Institute, cutting sodium (mostly from salt) in half would prevent about 150,000 fatal heart attacks and strokes annually. Cutting sodium levels in packaged and restaurant foods should be the number-one nutrition priority for the FDA (as it has been for the British Food Standards Agency). The FDA should begin both voluntary and regulatory actions:
 - The voluntary approach should consist of setting sodium targets for different categories of food and ask industry to meet those goals according to a specified timetable.
 - Rulemaking action should begin by revoking the "Generally Recognized as Safe" status of salt and any prior sanctions that exist – or adding maximum sodium levels in GRAS specifications and standards of identity – and then requiring manufacturers to reduce the amount of sodium in their products; the Daily Value noted on Nutrition Facts labels should be reduced from the current level of 2,400 mg to 1,500 mg (the limit recommended for most adults by the Institute of Medicine).
2. A second major cause of cardiovascular disease in the American diet is the presence of artificial trans fat from partially hydrogenated vegetable oil, another GRAS substance. While adding trans fat to Nutrition Facts labels and massive publicity have spurred many major manufacturers and restaurants to largely eliminate trans fat, a substantial number of foods still contain trans fat. That remaining trans fat is probably causing roughly 10,000 to 20,000 premature deaths annually. The FDA should:
 - Require restaurants to disclose the presence of artificial trans fat in their foods; failure to do so would be considered a violation of the misbranding section of the Food, Drug, and Cosmetic Act.
 - Initiate a rulemaking to revoke the GRAS status of partially hydrogenated vegetable oil and limit the amount of artificial trans fat to under 0.5 grams per serving, the amount the agency considers 0 grams trans fat.
3. To stop the proliferation of deceptive food labeling, the FDA should bring several lawsuits against obviously misleading labeling by leading manufacturers. That was done by Dr. David Kessler shortly after becoming the FDA Commissioner and the actions reduced the volume of misleading claims for more than a decade.